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EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
04/06/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/530,488	TJOTTA, ENOK	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/14/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28, 31-34, 37, 38, 40-60, and 64-70* is/are pending in the application.

4a) Of the above claim(s) *58,61 and 64-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,31-34,37,38,40-57,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed February 14, 2011 in response to the Office Action of October 13, 2010 is acknowledged and has been entered. Previously pending claims 1-27, 29, 30, 35, 36 and 39, 62, and 63 have been cancelled, claims 28, 32, 34, 47, 50-52 , 58-60, and 61 have been amended and new claims 64-70 have been added.

The amended claims 58, 61 and newly submitted 64-70 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Amended claim 58 is drawn to the method according to claim 52, wherein 4-OH-OPB is administered to a subject undergoing conventional cancer treatment including cytotoxins in order to prevent development of drug resistance. Amended claim 61 is drawn to a method for inhibition of specific testing an agent that has an activity on clonal cell growth, comprising the steps: a) selecting a specific clonal inhibitor or 4-OH-OPB, and screening substances selected from drugs, food, food additives, toxins, microbes, microbes, cosmetics natural stimulants or components from physiological or pathological processes, in order to be able to prevent neoplastic diseases and development of arteriosclerosis in a population;

b) testing the effect that different degrees of local collocation of cells have on the effect of said agent having an activity on clonal growth on cloning, said testing comprising:

i) transplanting tumor cells to an animal, or seeding experimental cell cultures with BHK21/cI3 or BHK21/CI3 cells transformed with polyoma virus; ii) treating said tumor cells in the animal or the cells in experimental cell cultures with said agent having an activity on clonal growth;

iii) determining the effect of said agent having an activity on clonal growth on cloning of said tumor cells or stimulated immune cells in the individual or the cells in experimental cell cultures;

c) testing said agent having an activity on clonal growth with an in vivo metastasizlng test to determine the effect of said agent having an activity on clonal growth on metastasizing cells, said step comprising:

i) injecting tumor cells in an animal to develop metastases, ascites or local tumors;

ii) applying the agent having an activity on clonal growth; and

iii) determining the effect of said agent having an activity on clonal growth to affect the liberation of cells, migration, and the ability to form local tumor;

d) evaluating the results obtained with steps a), b), and c; and e) determining whether said agent having an activity on clonal growth inhibits or stimulates clonal growth.

New claims 64-70 are drawn to a method preparing a pharmaceutical preparation, comprising: compounding 4-OH-OPB with a pharmaceutically acceptable carrier, wherein the preparation is for the treatment or prophylactics of psoriasis or diseases selected from arteriosclerosis, or from cancer, and wherein the pharmaceutical preparation for cancer is either for prophylaxis of malignant growth or for the treatment or prophylaxis of metastatic spread and local infiltration of malignant tumors.

The amended and new claims are drawn to distinct inventions because the originally examined claims were not drawn to either 1) the method according to claim 52, wherein 4-OH-OPB is administered to a subject undergoing conventional cancer treatment including cytotoxins in order to prevent development of drug resistance 2) a method comprising the step of selecting

a specific clonal inhibitor or 4-OH-OPB, and screening substances selected from drugs, food, food additives, toxins, microbes, microbes, cosmetics, natural stimulants or components from physiological or pathological processes, in order to be able to prevent neoplastic diseases and development of arteriosclerosis in a population or 3) a method of preparing a pharmaceutical preparation a method preparing a pharmaceutical preparation, comprising: compounding 4-OH-OPB with a pharmaceutically acceptable carrier, wherein the preparation is for the treatment or prophylactics of psoriasis or diseases selected from arteriosclerosis, or from cancer, and wherein the pharmaceutical preparation for cancer is either for prophylaxis of malignant growth or for the treatment or prophylaxis of metastatic spread and local infiltration of malignant tumors.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58, 61 and 64-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 28, 31-34, 37, 38, 40-57, 59, and 60 are currently being examined.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 55 remains rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in section 2 of the Office Action of October 13, 2010.

Applicants argue that the Office Action asserts that that some agents are enabled and described and some do not, including p-hydroxy- azobenzene, 2-Butyl-2-hydroxy-N-(4-hydroxy-phenyl)-N'-phenyl malonamide, 1,2-diphenyl-4-hydroxy-4-[2-(phenylsulfinyl)ethyl]- 3,5-pyrazolidinedione, and analogues thereof (such as 4-OH-OPB).

Applicant argues that although the point is not conceded, these recitations have been removed from the claims without prejudice in order to prosecute prosecution on the merits.

Applicant argues that regarding the rejections of claims 54-56 (pertaining to HIV and anti-viral treatment), support can be found at paragraphs [0226], [0242] and [0298] of corresponding publication US 2006/0121449 A1 as well as, e.g., in Example lla, which pertains to HSV.

Applicant argues that regarding the "seeding" limitation discussed at page 34 of the Office Action, claims 28 and 61 have been amended to better correspond to the support found at page 40 of the specification or to remove this limitation.

Applicant's arguments have been considered, but have not been found persuasive. The cited portion of the specification generally point to treatment of HIV related malignancies or HIV with 4-OH-OPB or treatment of HSV infected cells with 4-OH-OPB in culture. However, the cited support does not teach or suggest how to remove collocated infected cells in a subjected with chronic infections or AIDS. Given the difficulty in treating the infected cells taught in the art and in absence of the evidence to the contrary, undue experimentation would be required to use the method as claimed for the reasons previously set forth. This rejection was not drawn to the seeding limitation.

3. Claims 54-56 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in section 4 of the Office Action of April 22, 2010.

Applicant argues that although the point is not conceded, these recitations have been removed from the claims without prejudice in order to prosecute prosecution on the merits.

Applicant argues that regarding the rejections of claims 54-56 (pertaining to HIV and anti-viral treatment), support can be found at paragraphs [0226], [0242] and [0298] of corresponding publication US 2006/0121449 A1 as well as, e.g., in Example lla, which pertains to HSV.

Applicant argues that regarding the "seeding" limitation discussed at page 34 of the Office Action, claims 28 and 61 have been amended to better correspond to the support found at page 40 of the specification or to remove this limitation.

Applicant's arguments have been considered, but have not been found persuasive. The cited portion of the specification generally point to treatment of HIV related malignancies or HIV with 4-OH-OPB or treatment of HSV infected cells with 4-OH-OPB in culture. However, the cited support is not found persuasive because it does not teach or suggest the limitations of "wherein 4-OH-OPB is administered to a subject after said subject has been exposed or infected to HIV and before HIV infected cells proliferate", "wherein 4-OH-OPB is administered to a subject with chronic infections or AIDS after removing the collocated infected cells", and "wherein 4-OH-OPB is administered in combination with an anti-viral treatment to inhibit drug resistance" as previously set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 47-54, 56, and 57 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/00585 (Tjotta et al. 4 January 2001, IDS) evidenced by Szucs et al. (Bulletin World Health Org. 1988 66: 729-737) for the reasons set forth in section 5 of the Office Action of October 13, 2010.

Applicant argues that distinctions of the present invention over the previously applied art have been made of record in the application which, for brevity, are not repeated here.

Applicant argues that the present invention is directed at the utilization of 4-OH-OPB or its analogues for the treatment of diseases such as cancer. This can include:

• a) Inhibition or stopping development of metastases of local infiltration. Malignant diseases derived from T4 lymphocytes or Kaposi's sarcoma are not included.

• b) When using conventional chemotherapy, simultaneous use of 4-OH-OPB is expected to prolong the period of the effect of such chemotherapy since resistant tumor clones are not allowed to develop (see experiment 16).

Applicant argues that 4-OH-OPB and its analogues can be used for the treatment of HIV:

• a) New infections before development of congestion of cells infected with defect HIV that is unable to destruct the host cell.

• b) Older HIV infections or AIDS where the congestion of the cells containing defect virus has become too big. The effect of 4-OH-OPB is then suspended. In order to get 4- OH-OPB working again, the congestion of cells with defect HIV need to be drastically reduced.

Applicant argues that 4-OH-OPB and its analogues can be used for the treatment of psoriasis or treatment and prophylaxis of arteriosclerosis:

• a) Compounds that inhibit specific clonal growth of sparsely seeded cells, but not identical cells in the same culture that were collocated.

• b) Compounds that stimulate specific clonal growth of sparsely seeded cells, but not identical cells in the same culture that were collocated.

Applicant argues that compounds in contact with the body, inside or outside, should be tested along these lines since there are indications that compounds mentioned under a) will prolong life when reducing cancer or arteriosclerosis. Those under b) will probably behave in reverse order and increase the probability of contracting cancer or arteriosclerotic complications. Therefore, both of these aspects are important for public health.

Applicant argues that independent claim 28 has been amended to add an additional step: "a) selecting an agent selected from the group consisting of 4-OH-OPB, drugs, food, food additives, toxins, and microbes, or components from physiological or pathological processes, where said agents or components demonstrate specific inhibition or specific stimulation of clonal growth in only sparsely distributed cells, not in collocated areas of identical cells."

Applicant argues that it is respectfully submitted that the applied art alone or in combination does not anticipate or render unpatentable independent claims 28 and 61 of the present invention.

Applicant argues that particularly HOWELL et al. do not disclose or infer the use of 4-OH-OPB and do not seed their cells sparsely as in the sense of the present invention where a cell density gradient in agar culture made it possible to compare the effect on both sparsely and densely distributed cells in the same culture.

Applicant argues that the inventor of the present invention, Dr Tjøtta, has studied the applied art and wishes to submit the following observations.

Applicant argues that the invention of HOWELL et al. sets forth a method of sensitizing various types of cancer cells derived from different tissues of origin to various cytotoxic agents and augmenting the sensitivity of cancer cells to these cytotoxic agents. The invention provides a method to treat cancer and other cell proliferative diseases by the administration of a sensitizing agent prior to or concurrently with the administration of a cytotoxic agent.

Applicant argues that this is not the aim of my patent application:

i. Cytotoxic agents are not examined or included in any claim.

2. Only compounds that inhibit or stimulate growth of cells (normal, transformed (experiment no. 5)), cancer cells (experiment no. 7-9) or immune cells (experiment no. i0) that are seeded sparsely in soft agar (experiment no. 5) or that are mixed with other cells of other specificities (as the immune cells of the spleen (experiment no. i0)) or cells going to develop cancer (see last paragraph on page 42 and first paragraph on page 43) or cells going to spread from a malignant tumor in an individual (experiment no. 9) are included.

Applicant argues that Technically HOWELL et al. seed their cells sparsely at about 4000 cells in one ml in dishes of 3.5 cm in diameter, but they did not compare the effect of the studied compounds on sparsely seeded cells with the effect in collocated areas of identical cells. In my

experiments, however, often between 35000 and 144000 cells were seeded in wells of 15 mm in diameter in 0.3 ml top soft agar layer on a bottom agar layer of 0.3 ml.

Applicant argues that the top layer containing the cells was placed on a bottom layer cast at an oblique angle of about 12 degrees in order to create a cell density gradient in the top layer.

Applicant argues that the cell gradient on the side of the well with the minimal cell number contained only about ¼ of the total cell number of the well. However, the most sparsely distributed cell area on the same side of the well only contained very few cells.

This gradient made it possible to compare the effect on cell growth induced by a compound on both sparse and crowded areas in the same well. I only looked for compounds with specific inhibition or stimulation only on cells that were sparsely seeded and not on collocated identical cells.

Applicant argues that in addition I cannot find HOWELL et al. using 4-OH-OPB, the definitely best compound detected by the method described in my invention (published as WO 2004/055175 AI). 4-OH-OPB was the only compound among the studied ones that was able to rescue mice transplanted with Ehrlich carcinoma and completely stop the development of metastases (experiment no. 7-9). However, if the transplantable Ehrlich cancer developed tumors, 4-OH-OPB had no inhibiting effect on their growth (experiment no. 9).

Applicant argues that there are no indications either that 4-OH-OPB may be a sensitizing agent as described by Howell et al.

Applicant argues that cytotoxic agents are mentioned by me in connection with a quite different field. Since 4-OH-OPB stops the development of new clones (experiment no. 13), also tumor clones resistant to cytotoxic agents are expected to be included. Therefore, the effect of

treatment with cytotoxic agents also is expected to last longer before losing activity against a malignant disease if 4-OH-OPB is given simultaneously.

These observations are being resubmitted in the form of a Declaration.

Applicant argues that this in light of the traversal of record therefore demonstrate that not only anticipation or prima facie unpatentability has been demonstrated, but that the present invention yield unexpected results that would fully rebut any unpatentability that could be alleged.

Applicant's arguments have been considered, and have been found persuasive, in part. The Declaration of Enok Tjotta under 37 CFR 1.132 filed February 14, 2011 is sufficient to overcome the rejection of claims 59 and 60 based upon WO 01/00585.

However, the Declaration of Enok Tjotta under 37 CFR 1.132 filed February 14, 2011 is insufficient to overcome the rejection of claims 47-54, 56, and 57, based upon being anticipated by WO 01/00585 (Tjotta et al. 4 January 2001, IDS) evidenced by Szucs et al. (Bulletin World Health Org. 1988 66: 729-737 as set forth in the last Office action because: the declaration is not drawn to the teachings of WO 01/00585 and does not show a patentable distinction between the rejected claims and WO 01/00585. Additionally, although claim 28 has been amended, the 4-OH-OPB used by WO 01/00585 would inherently be a clonal mitotic inhibitor as claimed as it is the same compound claimed regardless of the method of identification.

5. Claims 47-53 remain rejected under 35 U.S.C. 102(b) as being anticipated by USPN 6,258,845 (Gerner et al. July 10, 2001) for the reasons set forth in section 6 of the Office Action of October 13, 2010.

Applicant argues as set forth above.

Applicant's arguments have been considered, and have been found persuasive, in part. The Declaration of Enok Tjotta under 37 CFR 1.132 filed February 14, 2011 is sufficient to overcome the rejection of claims 59 and 60 based upon USPN 6,258,845.

Applicant's arguments have been considered, but have not been found persuasive. The Declaration of Enok Tjotta under 37 CFR 1.132 filed February 14, 2011 is insufficient to overcome the rejection of claims 47-53 and 59 based upon being anticipated by USPN 6,258,845 as set forth in the last Office action because: the declaration is not drawn to the teachings of USPN 6,258,845 and does not show a patentable distinction between the rejected claims and USPN 6,258,845. Additionally, although claim 28 has been amended, the acetyl salicylic acid and ibuprofen used by USPN 6,258,845 would inherently be clonal mitotic inhibitors as claimed as they are the same compounds claimed regardless of the method of identification.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28, 31-34, 37, 38, and 40-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "and if the clonal inhibitor is 4-OH-OPB" in step iii). There is insufficient antecedent basis for this limitation in the claim as the antecedent portion of the claim does not refer to clonal inhibitors, but refers to agents.

Additionally in step iii), it is unclear and indefinite how one would one would **not** determine the effect of 4-OH-OPB of local tumors that were not inhibited. To determine if the local were tumors were not inhibited by 4-OH-OPB the effect of 4-OH-OPB would have had to determine the effect of 4-OH-OPB. Thus, the metes and bounds of the claim cannot be determined, rendering the claim indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28, 31-34, 37, 38, 40-57, 59, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection

The limitation ". . . not formation of local tumors that were not inhibited" in claims 28, 31-34, 37, 38, 40-57, 59, and 60 has no clear support in the specification and claims as originally filed. A review of the specification and original claims does not reveal support for these limitations. Thus the subject matter claimed in amended claims 28, 31-34, 37, 38, 40-57, 59, and 60 broadens the scope of the invention as originally disclosed in the specification as filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,674,888 (Polansky et al. 1997).

Polansky et al. teach enhancing the mitotic rate of cells in a subject with diclofenak. See claims 1-29. The diclofenak used by Polansky et al. is a clonal mitotic stimulator as claimed because it is the same compound claimed regardless of the method of identification. It is noted diclofenak is alternatively spelled with a “k” or "c" at the end of the word in the instant specification.

9. All other objections and rejections recited in the Office Action of 10/13/2010 are withdrawn in view applicants arguments, amendments, and/or the Declaration of Enok Tjotta under 37 CFR 1.132 filed February 14, 2011 .

10. No claims allowed.

11. Applicant’s amendment necessitated the new grounds of rejection. Thus **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/
Primary Examiner, Art Unit 1642